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Efficacy of Pre-emptive Dexamethasone and Diclofenac on Pain Control during Maxillary Alveolar Ridge Horizontal Augmentation using Cortical Shell Augmentation Technique: A Randomized Clinical Trial

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ABSTRACT

Background: Despite the popularity and success of autogenous cortical shell augmentation, it is a painful procedure, limiting its acceptance by patients specifically if general anesthesia is not a viable option. Aim: This study assessed the analgesic efficacy of co-administration of intramuscular diclofenac sodium and dexamethasone preoperatively. Material and Methods: Patients selected according to the inclusion criteria were randomly divided into 2 equal groups. A similar surgical augmentation technique was performed in both groups using autogenous cortical shell technique. The study group received an intramuscular injection of dexamethasone and diclofenac sodium before surgery, and pain level was measured using VAS (visual analogue scale of pain) immediately post-operative for both groups. Results: The mean Rank recorded in the control group (10.64) was greater than the mean value of the study group (4.36). This contrast was statistically significant (p=0.002). Conclusion: Preoperative administration of dexamethasone and diclofenac sodium was effective in controlling pain during cortical shell augmentation surgery.

1. INTRODUCTION

Pain is one of the undesirable sensations experienced by patients who undergo oral surgical procedures under local anesthesia as the peripheral nerve injury and inflammatory mediators released by the injured tissues stimulate pain perception by the brain[1].

Dental implants have become a reliable option for replacing missing teeth, The concern is that tooth loss followed by a considerable remodeling process results in reduced alveolar bone dimensions, and the risk of ridge collapse increases particularly in the anterior maxilla which predominantly has a thin labial plate of bone and even area of fenestration[2]. In such cases for proper esthetic and prosthetic implant placement, horizontal bone augmentation should be performed with simultaneous implant placement or in a staged approach depending on the available native bone and defect morphology according to Benic and Hammerle classification [3,4].

In the literature[5], various techniques have been advocated for bone augmentation such as distraction osteogenesis, ridge splitting, guided bone regeneration, bone block, cortical shell technique, or a combination approach. In the cortical shell technique, a thin autogenous bone block is used to restore an outer contour, allow for rapid revascularization and create a gap that is then filled with small particles of bone, along term follow-up after ridge augmentation showed excellent volume stability[6].

Usually, the autogenous cortical shell harvesting from an intraoral donor site in short-span cases and fixation to the defect area is performed under local anesthesia[7,8] In order to reduce the pain associated with this procedure and its inflammatory undesirable effect there are several analgesic protocols have been mentioned in the literature such as the use of cryotherapy, non-steroidal anti-inflammatory drugs, and corticosteroids, and to limit the production of inflammatory mediators responsible for nociceptive fibers stimulation and stop the inflammation cascade[9,10].

The purpose of this study was to investigate the impact of dexamethasone and sodium diclofenac as an antinociceptive treatment preoperatively.

2. MATERIAL AND METHODS

This clinical investigation was carried on 14 participants picked from clinic of oral and maxillofacial departments of Future university hospital according to the following inclusion and exclusion criteria.

Inclusion criteria: adult cooperative patients within an age range (20:50 years) with decreased alveolar ridge width less than 3.5 mm, healthy patient or patient with controlled systematic disease considered as (ASA class 1 and 2)

Exclusion criteria: patients in need of medical attention or patient under medication or medical condition may interfere with the dexamethasone or diclofenac absorption or effect, patients with poor oral hygiene, in case of infection in the recipient site.

The study's purpose was explained to the chosen patients, and informed consent was obtained all the procedure was conducted according to Helsinki declaration (2013) after approval of research ethics committee of Future university in Egypt. The participants were randomly separated into two groups using a specialized online software **(http://randomizer.org)**.

The control group: 7 patients performed the autogenous cortical shell augmentation procedure under local anesthesia without preoperative medications to control pain.

The study group: 7 patients received intramuscular injection of dexamethasone and diclofenac sodium preoperatively and underwent the same augmentation procedure steps as control group.

Preoperative evaluation includes proper detailed history taken, clinical examination to confirm patient fitting the inclusion criteria and radiographic examination for virtual procedure planning(figure.1).

For the study group intramuscular injection of Dexamethasone (sodium phosphate) 8mg amp, (and Voltaren (diclofenac sodium) 75 mg / 3 ML amp (Novartis company in Switzerlandone) immediately preoperative (figure.2).

All surgical procedures for both groups were performed under local anesthesia 4 ampoules of (artinibsa 40mg/0.01mg/ml, Inibsa, Barcelona, Spain).

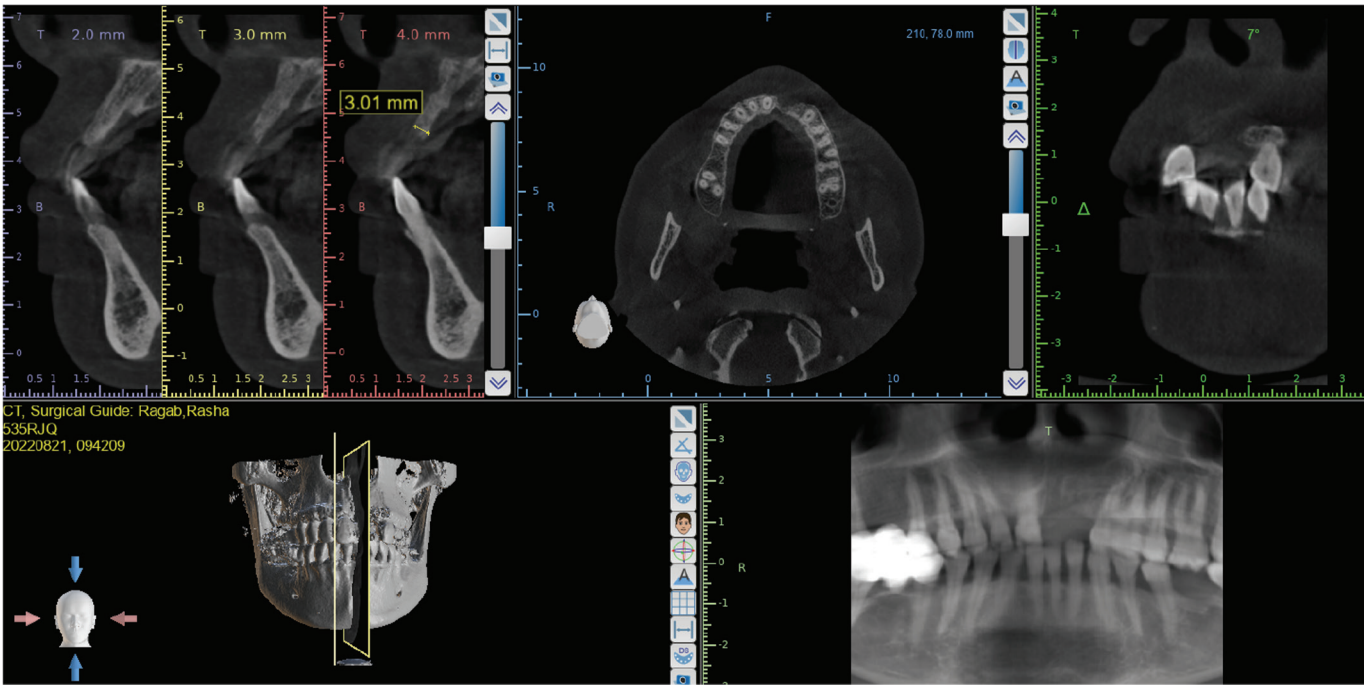

Figure (1) — Preoperative planning to assess the indication for augmentation.

Figure (2) —Dexamethasone and diclofenac sodium Ampoules

After infra orbital nerve block and area infiltration for hemostatic purposes a full thickness mucoperiosteal flap elevated and reflected first in the recipient site and soft tissue prepared by submucosal dissection to allow for non-tension soft tissue closure.

The cortical shell harvested from the symphysis area under mental nerve block and field infiltration, A vestibular incision performed from canine in one side to other side if indicated with caution to prevent labial branch of mental nerve injury followed by soft tissue reflection and cutting bone block using diamond wheel under copious saline irrigation according to the bone shell dimensions needed. The shell prepared outside patient mouth to fit the defect and smoothening of sharp edges to prevent graft dehiscence (figure. 3).

The cortical shell fixed in the defected area with titanium screws in manner creating a gap to be filled with bone particles autogenous collected from the same donor site mixed with xenogeneic bone then the recipient site sutured followed with the donor site (figure.4).

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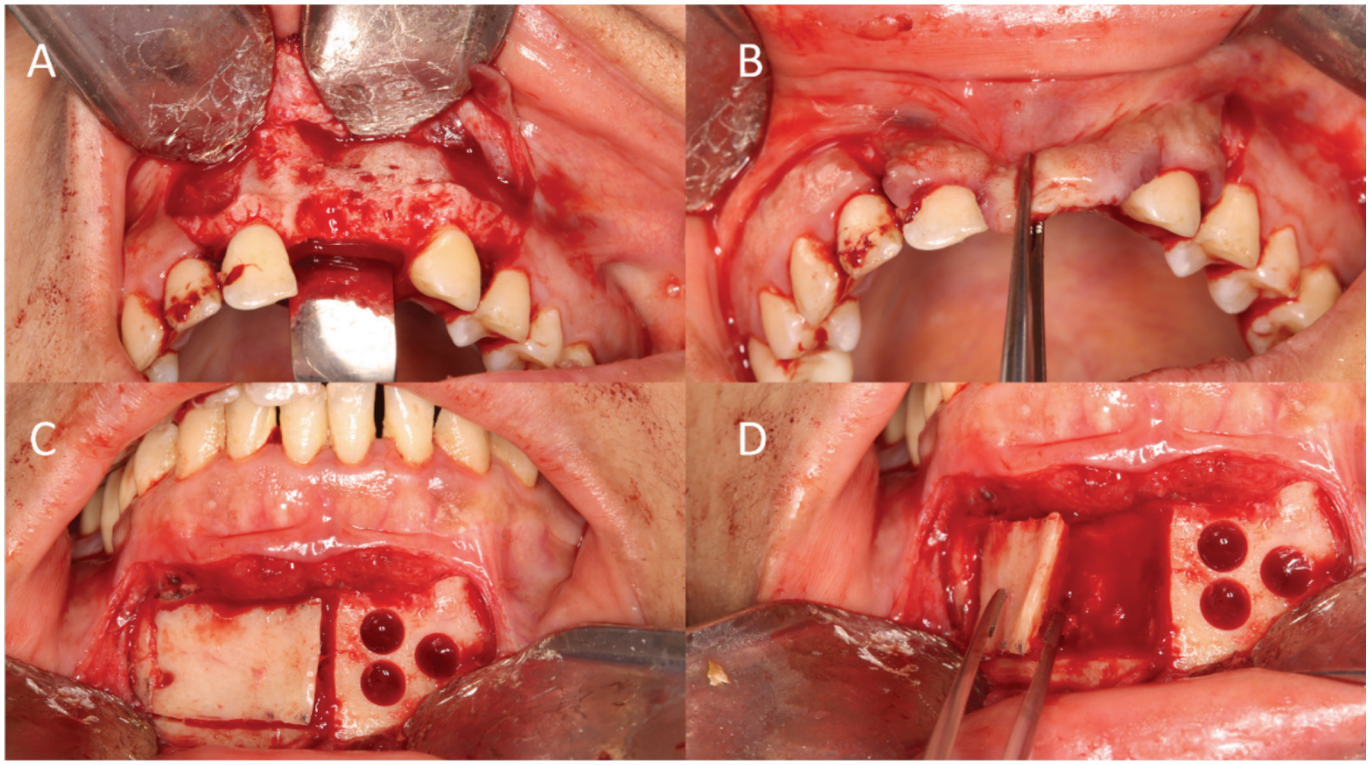

Figure (3) — Flap reflection and bone perforations to enhance vascularity(A), no soft tissue tension(B), bone shell hrvesting and particulate bone collection(C,D)

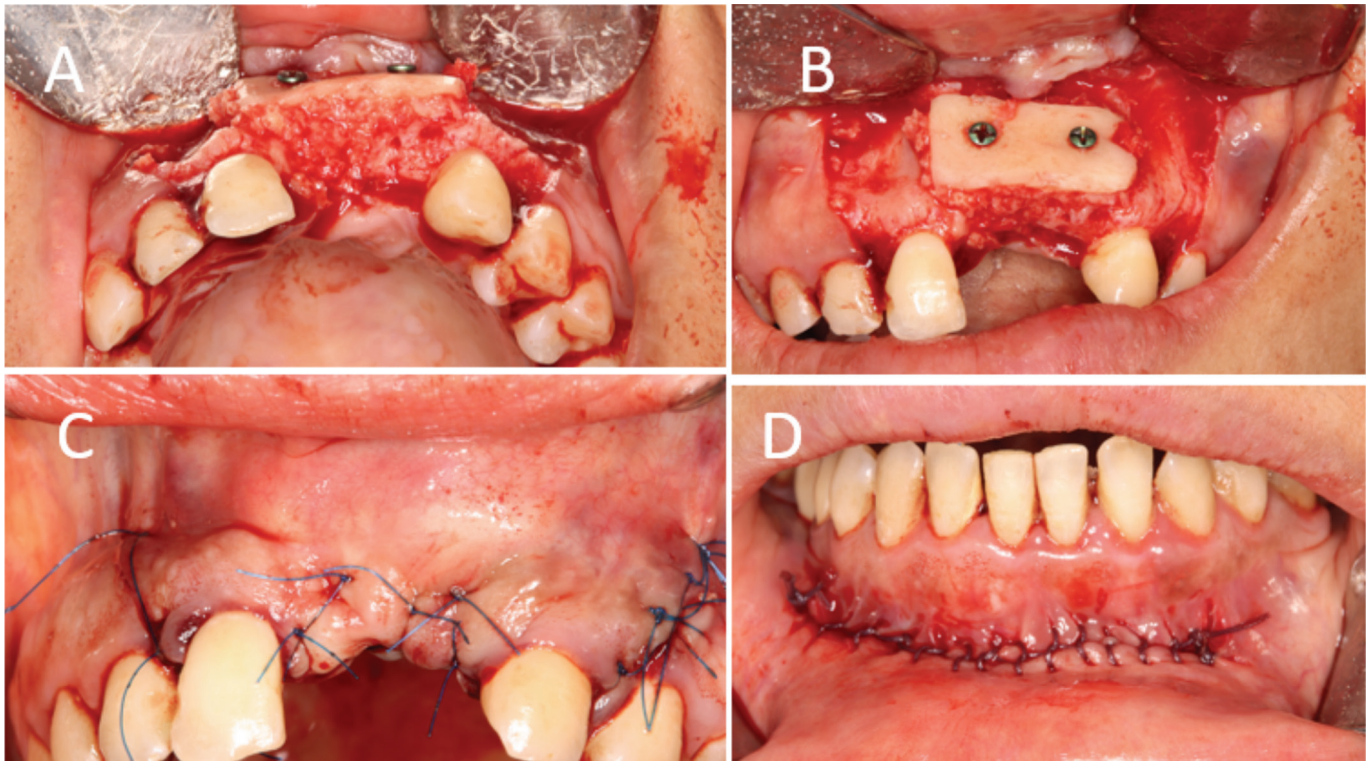

Figure (3) — Occlusal view after augmentation (A), frontal view showing titanium screw fixing the outer shell(B), suturing the recipient site (C), and finally suturing the donor site(D)

Using the same stopwatch from the incision to the last, the entire procedure's duration in minutes was recorded.

Assessment of pain was asked to perform immediately postoperative using a visual analogue scale questionnaire of pain 0 meaning least painful while 10 meaning a severe pain each patient asked to determine its own pain value (figure.5).

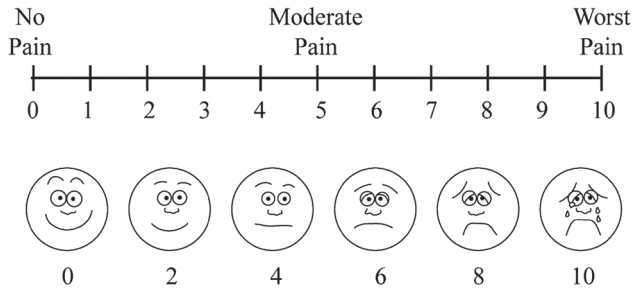

Figure (5) — Visual analogue scale of pain

Immediate postoperative medications and instructions include:

- Amoxicillin 875 mg /Clavulanic acid 125mg in a dose of one capsule every 12 hours for 5days.
- Non-steroidal anti-inflammatory drugs (Ibuprofen)400 mg at a dose of one tablet every 8 hours for 3days.
- Chlorhexidine gluconate solution as a mouthwash twice daily for one week to enhance plaque control.
- The patient will be asked to keep on a clear fluid diet for the first 24 hours then a soft diet to be maintained for the next day.
  - » Strict oral hygiene measures in the form of regular use of toothbrush and antiseptic mouthwash starting the day after surgery.
  - » Warm saline oral rinsing three times daily for one week

After four months the second CBCT was accomplished to determine a new ridge width and diameter of implant placement(figure.6).

Finally, Version 20 of the Statistical Package for Social Sciences (SPSS) was used for data management and statistical analysis. Numerical data were summarized using mean, standard deviation, median and range. Data were investigated for normality by assessing the data distribution and using Shapiro-Wilk tests and Kolmogorov-Smirnov. Mann Whitney U test was used to compare pain scale (non-parametric numeric variable) between groups. All p-values are two-sided. P-values ≤0.05 were considered significant.

3. RESULTS

Pain scale with a standard surgical procedure and almost same operation duration between both groups.

Operation duration in minutes

The mean operation duration (min.) in intervention group was (149.57±27.26), in comparison to (153.86±32.15) in control group, with no noticeable differences existed between the groups (p=0.793), (table 1, figure.7).

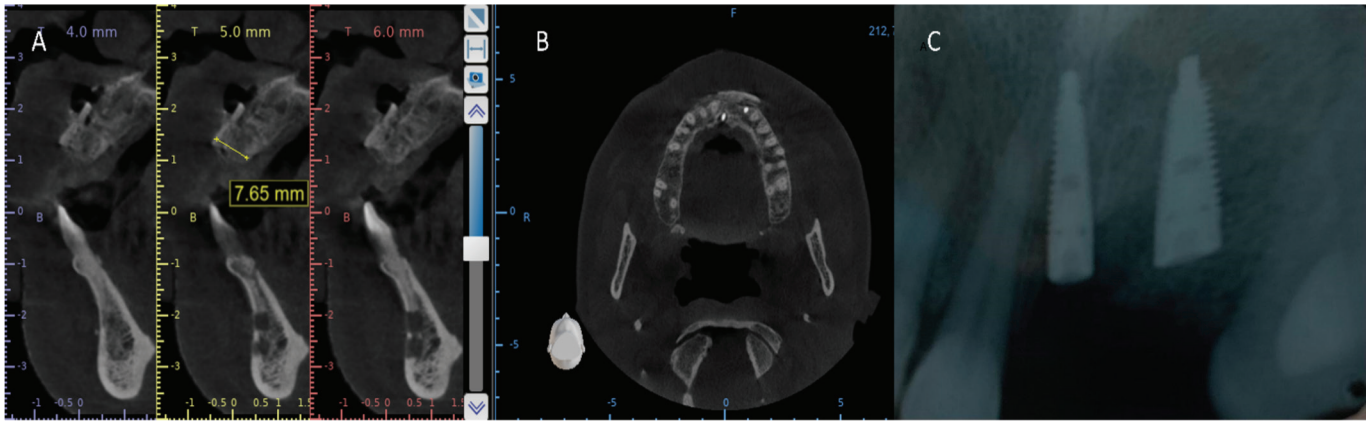

Figure (6) — Cross-section view showing the new ridge width(A), axial view for the augmented ridge before implant placement(B), periapical film after implant placement(C)

Table (1)

Operation duration (min.) in intervention and control groups (independent t test)

	Groups	Mean	Std. Dev	t	P value
Operation duration	Intervention group	149.57	27.26	.269	.793 ns
	Control group	153.86	32.15		

Significant level p≤0.05, ns=non-significant

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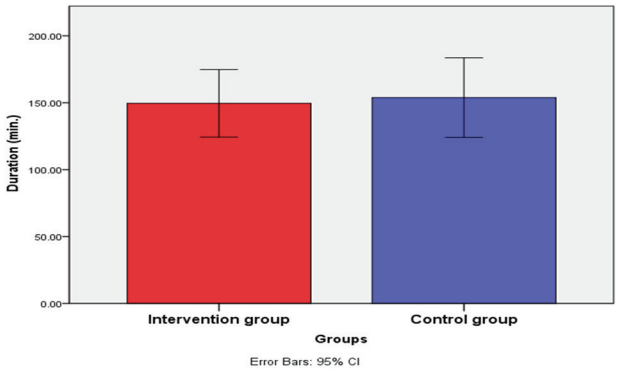

Figure (7) — Bar chart illustrating mean operation duration (min.) in both groups

Pain scale:

The control group recorded a median value =7 (range 5 to 10, mean 7±1.83). This value was greater than that of study group recording a median value =1 (range 0 to 6, mean 1.86±2.12).

Mann Whitney U test revealed that the mean Rank recorded in control group (10.64) was greater than the mean value of study group (4.36). This difference was statistically significant (p=0.002), (table 2, figure.8)

Table (2)

Descriptive statistics of pain scale and comparison between groups (Mann Whitney U test)

	Study group	Control group	P value
Mean Rank	4.36	10.64	
Median	1	7	0.002*
Mean ±Std. Deviation	1.86±2.12	7±1.83	
Minimum	0	5	
Maximum	6	10	

Significance level p≤0.05, *significant

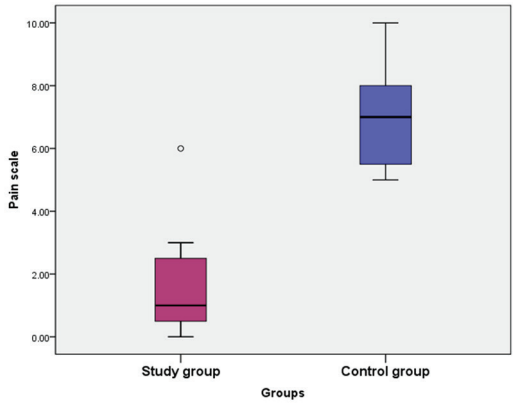

Figure (8) — Box plot illustrating median value and interquartile range of pain scale in study and control groups.

4. DISCUSSION

The pain perception is influenced by several factors including sex, age, psychological state, history of traumatic experiences, type of procedure, and duration, all of this have an impact on how painful something feels. [11]

Most of the researches were conducted for surgical extraction of impacted third molar or implant placement[12,13] as a common oral surgical procedure recently an augmentation procedure become popular operation to be performed on dental clinic simultaneously under local anesthesia [14]so, this study investigated the impact of analgesic on pain control during ridge augmentation procedure and autogenous bone grafting.

Dexamethasone (synthetic derivative of cortisol) can be administered in a variety of ways, including orally (as tablets) one hour prior to surgery or parenterally (as an injection) immediately prior to surgery because the parenteral technique has a faster onset and higher blood level than the oral route[15], and that was considered in our work.

It is an anti-inflammatory medication that blocks phospholipase-A2, which in turn affects the production of leukotrienes and prostaglandins and lowers polymorphonuclear leukocyte chemotaxis. Additionally, it prevents endothelial cells from producing nitric oxide and free oxygen radicals. Additionally, numerous proinflammatory cytokines implicated in the inflammatory process and immunological response, including interleukin-1b (IL-1b), IL-6, IL-8,IL -12, and IL-18, and tumor necrosis factor-alpha (TNF-a), can be downregulated by dexamethasone[16].

So, when compared to NSAIDs, corticosteroids continue to be a great option for preemptive analgesia in third-molar operations. however, The presurgical mixture of both medications does relieve the postoperative symptoms, particularly the initial hours of intense pain according to the meta-analysis performed by **Gustavo et al**[17].

Also, according to the literature the use of dexamethasone and diclofenac sodium together has a synergistic effect on pain relief better than the use of diclofenac sodium or potassium alone[18,19].

In this study the results of the intervention group revealed mild intraoperative pain, recording a median value =1 (range 0 to 6, mean 1.86±2.12).in comparison with control group recorded a median value =7 (range 5 to 10, mean 7±1.83). which was caused by the analgesic effects of preoperatively administered dexamethasone and diclofenac sodium intramuscular injection as analgesic and anti-inflammatory medications. These medications act by inhibiting the arachidonic acid pathway, which triggers the production of chemical mediators such as histamine, kinins, and prostaglandins for pain and inflammation response. Therefore, the preemptive medication helps to reduce this mediator's blood stream concentration and pain perception. This observation is comparable to a study by **Simone et al,** [21]

Wuolijoki et al[20]**,** evaluated the effects of preoperative versus postoperative intramuscular injections of diclofenac sodium 75 mg, evidencing that the prior administration had a superior impact on pain reduction than the postoperative administration.

5. CONCLUSION

Within the constraints of this study, it was found that immediately intramuscular injection of steroidal anti-inflammatory drugs and diclofenac sodium prior to surgery was effective in reducing patients' perceptions of pain, making it a worthwhile alternative for anxious patients who refuse general anesthesia during ridge augmentation surgeries.

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